

II. Amendments to the Claims

This listing of claims replaces without prejudice all prior versions and listings of claims in the application:

Listing of Claims:

Claims 1–63 (Cancelled).

64. (Currently Amended) A process for the treatment of a patient with ~~manufacture of~~ a monophasic pharmaceutical composition comprising devazepide comprising the steps of:

- a) providing a therapeutically effective amount of devazepide that is sufficient to deliver a daily dosage of devazepide of from 25 µg/kg/day to 0.7 mg/kg/day ~~up to 0.7 mg/kg/day~~;
- b) providing from 0.4 mg to 1.6 mg ~~a suitable amount~~ of a pharmaceutically acceptable surfactant; and
- c) combining the devazepide and the surfactant so as to obtain the monophasic pharmaceutical composition.

Claims 65–128 (Cancelled).

129. (Currently Amended) The process of claim 64, wherein the daily dosage of devazepide is from 0.07 mg/kg/day to 0.29 mg/kg/day ~~25 µg/kg/day to 0.7 mg/kg/day~~.

130. (Currently Amended) The process of ~~claim 129~~, claim 64, wherein the daily dosage of devazepide is from 50 µg/kg/day to 0.5 mg/kg/day.

131. (Previously Presented) The process of claim 64, wherein the composition is in a liquid form.

132. (Previously Presented) The process of claim 64, wherein the composition is in a solid dosage form.

133. (Previously Presented) The process of claim 132, wherein the composition is in the form of a tablet.

134. (Previously Presented) The process of claim 132, wherein the composition is in the form of a flowable powder in a capsule.

135. (Withdrawn) The process of claim 64, wherein the opioid is selected from the group consisting of morphine, naloxone, meperidine, butorphanol, pentazocine, morphine-6-glucuronide, codeine, dihydrocodeine, diamorphine, dextropropoxyphene, pethidine, fentanyl, alfentanil, alphaprodine, buprenorphine, dextromoramide, diphenoxylate, dipipanone, heroin, hydrocodone, hydromorphone, levorphanol, meptazinol, methadone, metopon, nalbuphine, oxycodone, oxymorphone, phenadoxone, phenazocine, remifentanyl, tramadol, and salts thereof.

136. (Withdrawn) The process of claim 135, wherein the opioid is selected from the group consisting of hydromorphone, oxycodone, morphine, fentanyl, and salts thereof.

137. (Withdrawn) The process of claim 136, wherein the opioid is morphine or morphine sulphate.

138. (Withdrawn) The process of claim 135, wherein the opioid is fentanyl, or a salt thereof.

139. (Cancelled)

140. (Currently Amended) The process of claim 64, ~~claim 139~~, wherein the surfactant is a hydrophilic surfactant.

141. (Withdrawn) The process of claim 140, wherein the hydrophilic surfactant is an ionic or a non-ionic surfactant.

142. (Withdrawn) The process of claim 141, wherein the hydrophilic surfactant is a non-ionic surfactant selected from the group consisting of alkylglucosides; alkylmaltosides; alkylthioglucosides; lauryl macrogolglycerides; polyoxyethylene alkyl ethers; polyoxyethylene alkylphenols; polyethylene glycol fatty acids esters; polyethylene glycol glycerol fatty acid esters; polyoxyethylene sorbitan fatty acid esters; polyoxyethylene-polyoxypropylene block copolymers; polyglycerol fatty acid esters; polyoxyethylene glycerides; polyoxyethylene sterols, derivatives, and

analogues thereof; polyoxyethylene vegetable oils; polyoxyethylene hydrogenated vegetable oils; reaction mixtures of polyols and at least one member of the group consisting of fatty acids, glycerides, vegetable oils, hydrogenated vegetable oils, and sterols; tocopherol polyethylene glycol succinates; sugar esters; sugar ethers; sucroglycerides; and mixtures thereof.

143. (Cancelled)

144. (Withdrawn) The process of claim 139, wherein the surfactant is a lipophilic surfactant.

145. (Withdrawn) The process of claim 144, wherein the lipophilic surfactant is selected from the group consisting of alcohols; polyoxyethylene alkylethers; fatty acids; bile acids; glycerol fatty acid esters; acetylated glycerol fatty acid esters; lower alcohol fatty acids esters; polyethylene glycol fatty acid esters; polyethylene glycol glycerol fatty acid esters; polypropylene glycol fatty acid esters; polyoxyethylene glycerides; lactic acid derivatives of mono/diglycerides; propylene glycol diglycerides; sorbitan fatty acid esters; polyoxyethylene sorbitan fatty acid esters; polyoxyethylene-polyoxypropylene block copolymers; transesterified vegetable oils; sterols; sterol derivatives; sugar esters; sugar ethers; sucroglycerides; polyoxyethylene vegetable oils; polyoxyethylene hydrogenated vegetable oils; reaction mixtures of polyols and at least one member of the group consisting of fatty acids, glycerides, vegetable oils, hydrogenated vegetable oils, and sterols; and mixtures thereof.

146. (Withdrawn) The process of claim 139, wherein the surfactant is a glyceride.

147. (Withdrawn) The process of claim 146, wherein the glyceride is selected from the group consisting of vegetable oils, fish oils, animal fats, hydrogenated vegetable oils, partially hydrogenated vegetable oils, synthetic triglycerides, modified triglycerides, fractionated triglycerides, and mixtures thereof.

148. (Previously Presented) The process of claim 64, wherein the surfactant is selected from the group consisting of alkyl sulphosuccinates, alkyl sulphates and alkyl ammonium salts.

149. (Previously Presented) The process of claim 148, wherein the surfactant is selected from the group consisting of docusate sodium (dioctyl sodium sulphosuccinate), sodium dodecyl sulphate and tetradecyltrimethyl ammonium bromide.

150. (Previously Presented) The process of claim 64, wherein the composition further comprises one or more fillers selected from the group consisting of lactose, mannitol, talc, magnesium stearate, sodium chloride, potassium chloride, citric acid, spray-dried lactose, hydrolysed starches, starch, microcrystalline cellulose, cellulose, sorbitol, sucrose, sucrose-based materials, icodextrin, calcium sulphate, dibasic calcium phosphate, dextrose and mixtures thereof.

151. (Previously Presented) The process of claim 150, wherein the composition comprises an amount of devazepide of 1.25 mg, an amount of surfactant of 0.1 mg and 148.65 mg, of a filler.

152. (Previously Presented) The process of claim 150, wherein the composition comprises an amount of devazepide of 2.5 mg, an amount of surfactant of 0.2 mg and 297.3 mg of a filler.

153. (New) The process of claim 150, wherein the one or more fillers is corn starch.

154. (New) The process of claim 64, further comprising providing opioid to the patient.

155. (New) The process of claim 154, wherein the opioid is morphine or morphine sulphate.